

10090811

AUG 27 2009

510(K) Summary

(a as required by 21 CFR Part 807.87(h))

Summary Preparation Date:

Company Name: NeuroLogica Corporation
Company Address: 14 Electronics Avenue
Danvers, MA 01923
Contact Person: Donald D. Fickett
Director of Regulatory/Quality Assurance
Telephone: (978) 564-8523
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Trade name: NeuroLogica Corporation InSPira HD™
Common name: Single photon emission computed tomography system
Classification name: SPECT (21 CFR 880.1200, Product Code KPS)
Classification: II

Predicate Devices:

1. GE Medical Systems, Millennium Mobile MG Imaging System - K022240
2. Union Carbide, Imager, Body Section, Radionuclide - K780395
3. NeuroLogica Corporation, CereTom™ Model NL3000 - K051765

Device Description:

The InSPira HD™ is a mobile single photon computed tomography system comprised of focused collimators to acquire volumetric x-ray data primary of the head and neck. This system is intended to be utilized by appropriately trained healthcare professionals to image and measure the distribution of radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body. With the exception of an x-ray source, materials and construction are equivalent to the CereTom and are compliant with CISPR11, IEC 60601-1 and associated collateral standards and applicable sections of 21CFR Subchapter J.

Substantial Equivalence Comparison

The inSPira HD™ has similarities/differences to GE Medical Systems' Millennium Mobile MG Imaging System and eNTEGRA Workstation (K022240) as follows:

Similarities

1. Diagnostic imaging of appropriate single photon emission radiopharmaceuticals
2. Sodium Iodide(NaI) crystal detectors and photo multiplier tubes
3. Lead(Pb) Collimators
4. Gantry Apparatus to move detectors around patient
5. Detector electronics which count single photon events
6. Laser alignment
7. Computers and algorithms to compute tomographic images
8. Display(DICOM 3.0) and connectivity(PACS) capability
9. Radiolucent patient support (carbon graphite)
10. Emergency Stop switch
11. Mobility via transport wheels

Differences:

1. inSPira HD™ utilizes "focused" collimators, Millenium VG utilizes "pinhole" collimators
2. inSPira HD™ detectors are enclosed in covers thus eliminating hazard of patient entanglement. Millenium VG has open detectors
3. inSPira HD™ limited to anatomy that can be imaged within a 21cm field of view, primarily brain. Millenium VG has 60 cm field of view thus allowing full body applications.
4. inSPira HD™ scans in a continuous spiral motion. Millenium VG moves in a rectilinear fashion.
5. Items 1 and 4 above allow the inSPira HD™ to have better reconstructed resolution/sensitivity for brain sized anatomy than the Millenium VG (see table and images)
6. inSPira HD™ only performs 3D tomographic (SPECT) scans. The Millenium VG performs 3D (SPECT) and 2D (gamma camera) scans.
7. inSPira HD™ has centipede tractor system to move along floor. Millenium VG has moving patient table.

The inSPira HD™ has similarities/differences to the predicate device, Union Carbide Imager, Body Section, Radionuclide (K780395) as follows:

Similarities

1. Diagnostic imaging of appropriate single photon emission radiopharmaceuticals
2. Sodium Iodide(NaI) crystal detectors and photo multiplier tubes
3. Lead(Pb) "Focused" Collimators
4. Gantry Apparatus to move detectors around patient (enclosed)
5. Detector electronics which count single photon events
6. Laser alignment
7. Computers and algorithms to compute tomographic images
8. Radiolucent patient support (carbon graphite)
9. Emergency Stop switch
10. 21 cm field of view (brain sized)
11. 3D scanning (no 2D)
12. Improved resolution and sensitivity to pinhole SPECT systems

Differences:

1. inSPira HD™ has mobility(4 wheels and battery system) allowing for movement from multiple locations.
2. inSPira HD™ scans in a continuous spiral motion. Union Carbide moves in a rectilinear fashion.
3. inSPira HD™ has centipede tractor system to move along floor. Union Carbide has moving patient table.
4. inSPira HD™ has more PMTS/crystals (72 vs. 12) and focused collimator holes are smaller in Z direction giving better resolution in Z axis.
5. inSPira HD™ is considerably smaller and lighter.
6. inSPira HD™ has DICOM 3.0 and PACS connectivity.

The inSPira HD™ has similarities/differences to our CereTom X-ray Computed Tomography System (K051765) include:

Similarities

1. Mobility(4 wheels and battery system) allowing for movement from multiple locations within hospital and private healthcare facilities
2. Identical construction methods
3. Radiolucent scan board attachable to various medical beds/stretchers
4. Centipede tractor system which moves scanner along floor while scanning
5. Laser Alignment
6. Display(DICOM 3.0) and connectivity(PACS) capability
7. Emergency Stop switch
8. Performs scan with small field of view (brain sized)

Differences

1. CereTom is CT with X-ray generation system. inSPira HD™ is SPECT and does not generate x-rays.
2. inSPira HD™ is heavier (2x).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

AUG 27 2009

Mr. Donald D. Fickett
Director of Regulatory /Quality Assurance
Neurologica Corporation
14 Electronics Avenue
DANVERS MA 01923-1011

Re: K090811

Trade/Device Name: InSPira HD™
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: July 6, 2009
Received: July 9, 2009

Dear Mr. Fickett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

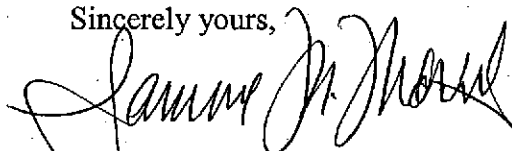
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name.

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) NUMBER (IF KNOWN):

K090811

DEVICE NAME: InSPira HD™

SPONSOR NAME: NeuroLogica Corporation

INDICATIONS FOR USE:

The inSPira HD™ is intended to produce images depicting the anatomical distributions of single photon emitting radioisotopes within the human body for interpretation by medical personnel for anatomy that can be imaged in the 21cm field of view, primarily brain.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use x
(Per 21 CFR 801.109)


OR

Over-The-Counter-Use ____
(Optional Format 1-2-96)

(Division Sign-Off)

Division of Reproductive, Abdominal,
And/Or Radiological Devices

510(k) Number _____



(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K090811